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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gruber, et al.
Serial No.: 09/284,697
Filed: July 6, 1999
For: PANCREATIC LIPASES AND/OR RECOMBINANT COLIPASES AND DERIVED POLYPEPTIDES PRODUCED BY PLANTS, METHODS FOR OBTAINING THEM AND USE THEREOF

Examiner: Einsmann, J.
Group Art Unit: 1655
Docket: 1149-2
Dated: September 24, 2001

Assistant Commissioner for Patents
Washington, DC 20231

I hereby certify this correspondence is being deposited w the United States Postal Service as first class mail, postp in an envelope, addressed to: Assistant Commissioner fo Patents, Washington, D.C. 20231 on September 24, 2001

Dated: 9/24/01 / J. Ch.

AMENDMENT

Sir:

This Amendment is being filed in response to the Office Action mailed March 22, 2001. Applicants respectfully request that this Amendment be entered into the above-identified file.

IN THE SPECIFICATION:

Please cancel the specification, without prejudice, and add the attached substitute specification in accordance with 37 C.F.R. 1.125(b).

IN THE CLAIMS:

27. (Amended) A recombinant nucleotide sequence comprising a sequence coding for an element of the pancreatic lipase-colipase complex, or a derivative of the element; a promoter; and a transcription terminator; wherein the promoter and transcription terminator are recognized by the transcriptional machinery of the plant cells, and wherein the element, or the derivative of the element, is suited for use as a pharmaceutical composition or a functional food.

D1

28. The recombinant nucleotide sequence according to Claim 27 wherein the element of the pancreatic lipase-colipase complex is pancreatic lipase.

31. A vector comprising the nucleotide sequence of Claim 27 or 30.

32. A host cell transformed by a vector in accordance with Claim 31.

33. (Amended) A method for obtaining an element of recombinant pancreatic lipase-colipase complex, or derivative of the element, wherein the method comprises: transforming a plant cell by incorporating the recombinant sequence according to Claim 27 into the genome of the cell; and recovering the element, or the derivative of the element, wherein the element, or the derivative of the element, is suited for use as a pharmaceutical composition or a functional food.

D2

34. The method of Claim 33 wherein the recovery comprises extraction.

35. The method according to Claim 33 wherein the element of the pancreatic lipase-colipase complex is pancreatic lipase.

39. A genetically transformed plant or part of the plant, wherein the plant or plant part contains at least one recombinant nucleotide sequence according to Claim 27 or 30.

40. The plant part according to Claim 39 selected from the group consisting of leaves, fruits, seeds and plant cells.

41. The plant according to Claim 39 selected from the group consisting of colza, tobacco, maize, pea, tomato, carrot, wheat, barley, potato, soybean, sunflower, lettuce, rice, alfalfa and beetroot.

57. (New) The recombinant nucleotide sequence according to Claim 28 wherein the element of the pancreatic lipase-colipase complex is human pancreatic lipase.

D3

58. (New) The method according to Claim 35 wherein the element of the pancreatic lipase-colipase complex is human pancreatic lipase.

REMARKS

In the previous Amendment filed on February 20, 2001, Claims 1-26 were cancelled and new Claims 27-56 were added. In response to a restriction requirement, the group of claims drawn to a polynucleotide and methods of expressing pancreatic lipase were elected. The Examiner deemed Claims 27, 28, 31-35 and 39-41 as being in this group. Accordingly these claims are being considered for prosecution.

Objections to the Specification

A few objections were made to the Specification. In particular, an objection was made to the spacing of the lines of the specification. (Office Action, page 2, paragraph 5.) Also, an objection was made since the specification does not contain an abstract. (Office Action, page 3, paragraph 8.) Finally, an objection was made to the French text appearing on page 66 of the specification. (Office Action, page 3, paragraph 8.)

The Applicants provide a substitute specification under 37 CFR 1.125(b) to overcome these objections. The substitute specification has the double-spaced format and standard margins as set forth by the United States Patent and Trademark Office. An abstract has been added. The French text has been deleted.

Along with the substitute specification, the Applicants have provided a marked-up copy of the substitute specification showing the matter being added to or deleted from the specification of record. The added matter is underlined; and the deleted matter is struck through.

Except for the addition of an abstract and deletion of the French text, the text of the substitute specification is exactly the same as the text of the original specification. The substitute specification contains no new matter.

Objections to the Sequence Listing

The Examiner states that SEQ ID NOs: 15 and 16 are new matter and requests cancellation of these sequences from the Sequence Listing.

The Applicants cancel SEQ ID Nos: 15 and 16. A new Sequence Listing, in both paper and computer-readable form, in which SEQ ID NOs: 15 and 16 have been deleted, will be provided shortly.

Rejection under 35 U.S.C. §103

Claims 27-28, 31-35 and 39-41 have been rejected under 35 U.S.C. §103 as being obvious over Willmitzer et al. (WO 92/01042) in view of Lowe et al (J. Biological Chem., 1989, 264(33): 20042-20048).

The Examiner states that Willmitzer et al. teach transgenic plants expressing **industrial enzymes**, and methods for the production of industrial enzymes in plants. The Examiner also states that Willmitzer et al. teach that lipases are among the industrial enzymes suggested for production by the described methods. (Office Action, page 4, paragraph 10.)

Willmitzer et al. define industrial enzymes on page 1, lines 8 to 20, as follows:

> Industrial enzymes are enzymes which are useful in industrial processes or which are components of industrial products. Thus, for instance ...lipases may be used in detergents as well as in the synthesis of lipids or other processes of organic synthesis...

Willmitzer et al. neither describe nor suggest a nucleotide sequence that encodes a pharmaceutically active pancreatic lipase, or a pharmaceutically active polypeptide derived from such a lipase. In fact, by specifically defining the enzymes of their application as "industrial," Willmitzer et al. teach away from using nucleic acid sequences in plants to encode a lipase that would be suited for use as a pharmaceutical composition or as a functional food.

In contrast, the present claims, as amended, recite that the element of **pancreatic lipase**, or the derivative of the element, is suited for use as a **pharmaceutical composition** or a **functional food**. In particular, Claim 27 has been amended to describe a nucleotide sequence as coding for an element of a pancreatic lipase-colipase complex which is suited for such a use. Similarly, Claim 33 has been amended to describe a method of obtaining an element of a pancreatic lipase-colipase complex which is suited for such a use. Support for these amendments are throughout the specification including, for example, on page 1, lines 5-7.

Moreover, Willmitzer et al. merely enumerate industrial lipases as one of 26 other enzymes. Their only specific teaching is drawn to the expression of two types of proteases in plants. Thus, there is no teaching in Willmitzer et al. to suggest the selection of lipases over any other of the enzymes taught for plant expression. Furthermore, there is no teaching in Willmitzer et al. to suggest the selection of pancreatic lipase.

Additionally, there is no teaching that would motivate one of skill in the art to select a human pancreatic lipase from the numerous lingual, gastric, and bile salt activated lipases from the myriad of species in which they may be found. See new Claims 57 and 58.

Accordingly, it would not have been obvious to a skilled artisan to use the pharmaceutically active human pancreatic lipase sequence disclosed by Lowe et al. in the method pertaining to industrial enzymes disclosed by Willmitzer et al.

In fact, Lowe et al. is non analogous art with respect to both Willmitzer et al. and the claimed invention. Therefore, Lowe et al. should not be treated as prior art with respect to the claimed invention.

In re Clay, 23 USPQ2d 1058 at 1060 (Fed. Cir. 1992) sets forth the two criteria for determining whether prior art is analogous art to a claimed invention. Application of these criteria to Lowe et al. follows.

The first criterion is "whether the art is from the same field of endeavor, regardless of the problem addressed." The present invention relates to the production of pancreatic lipases by plants. The Willmitzer et al. reference relates to the production of industrial enzymes by transgenic plants. On the other hand, Lowe et al. relates to the mechanism of action of lipase at a molecular level. (See p. 20042, Col. 2, 4th full paragraph.) Thus, clearly the field of the present invention and the field of Willmitzer et al. are not the same as the field of Lowe et al.

The second criterion is evaluated if the reference at issue is found not to be within the field of the inventor's endeavor. The second criterion is "whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." The present invention and the Willmitzer et al. reference address the problem of expressing

enzymes in transgenic plants. On the other hand, Lowe et al. do not address such a problem. In fact, Lowe et al. do not even mention transgenic plants.

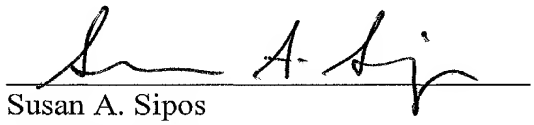
Thus, Lowe et al. is clearly non analogous art with respect to both Willmitzer et al. and the present claims. Consequently, Lowe et al. should not be treated as prior art with respect to the present invention.

Accordingly, Applicants respectfully request that the §103 rejection be withdrawn.

CONCLUSION

In view of the above amendments and remarks, this application is now believed to be in condition for allowance. If the Examiner believes that a telephone discussion with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney at the telephone number provided below.

Respectfully submitted,



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